

# **Annual General Meeting** Shareholder Presentation

22 November 2018, Perth, Western Australia

BUILDING A GLOBAL DIAGNOSTICS BUSINESS

ASX: PIQ



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## BUILDING A GLOBAL DIAGNOSTICS BUSINESS

ENORMOUS MARKET	ORMOUS MARKET PromarkerD, a predictive test for diabetic kidney disease is being rolled out now. 42 adults have diabetes globally. Territories <u>already licenced</u> capture 47m diabetes suffere		
<b>DE-RISKED CLINICALLY</b>	PromarkerD clinical studies completed successfully and validated by peer review.		
COMMERCIALLY READY	Licensing deals for PromarkerD have been recently executed in USA, Mexico, Spain & Dominican Republic. <u>Sales imminent</u> .		
GLOBAL SCALABILITY	PromarkerD is being rolled out through established diagnostic laboratories under license/royalty agreements. Multiple territories expected to be generating sales Q1 2019.		
NO COMPETITION	PromarkerD is the world's only commercial test for predicting the onset of diabetic kidney disease. Patented globally.		
DEEP PIPELINE	PromarkerD is the first commercial application of the company's platform technology. There is evidence that the technology could be applied to Endometriosis, Gastro, Asthma & Lung Disease - all major market opportunities.		
LEAN AND SCALABLE	Low fixed costs, strong balance sheet and <u>already generating A\$2.2m+ income</u> . Additional major territories under discussion. Truly a global opportunity.		
ALIGNED MANAGEMENT	Highly credentialed and experienced Board and Management that are aligned with shareholders. Founder & MD, Dr Richard Lipscombe holds 23.7% - Directors hold 35%.		



## CORPORATE OVERVIEW

CAPITAL STRUCTURE – 21/11/2018	
ASX code	PIQ
Share Price	\$0.355
Shares on issue	80m
Market capitalisation	\$28.4m
Cash/Receivables	\$3.8m
Enterprise Value	\$24.2m
Revenue & other income – FY18	\$2.2m
Monthly Burn	\$100k & decreasing

MAJOR SHAREHOLDERS			
Richard Lipscombe (Managing Director)	23.7%		
Dunlop/Randolph Res PL	7.2%		
XYLO PL	6.3%		
Directors Hold	35%		
Top 20 Shareholders	56%		





## **PROTEOMICS Vs TYPICAL BIOTECHS**

### ALL THE UPSIDE WITHOUT THE CLINICAL RISKS, COSTS & EXTENDED TIMELINES

Features	PIQ	<b>Typical Biotechs</b>
Enormous markets	$\checkmark$	$\checkmark$
Minimal clinical risk	$\checkmark$	X
No waiting for results	$\checkmark$	X
Short clinical development (for new products)	$\checkmark$	X
No binary outcome	$\checkmark$	X
Licensing deals executed	$\checkmark$	X
Commercially ready product(s) launch imminent	$\checkmark$	X
Existing revenues and low cash burn	$\checkmark$	X
No need for additional capital to be raised	$\checkmark$	X
Platform technology	$\checkmark$	Potentially
Peer reviewed	$\checkmark$	Potentially
Tight capital structure	$\checkmark$	Potentially



## THE PROMARKER TECHNOLOGY

### **PLATFORM TECHNOLOGY : PROMARKER<sup>™</sup>**

#### **PromarkerD – DIABETIC KIDNEY DISEASE TEST**

- PromarkerD predictive test for diabetic kidney disease up to four years in advance
- Licensing deals executed in USA, Mexico, Spain & Dominican Republic
- Enormous Market First Revenues imminent

#### **OTHER POTENTIAL DIAGNOSTICS**

- Proven platform to create diagnostic tests
- Pipeline tests: Endometriosis, Gastro, Asthma & lung disease - all major global opportunities

#### **ANALYTICAL SERVICES**

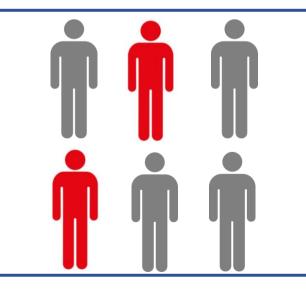
- Best in class Quality Control testing
- Biosimilars & biologics
- Pharmacokinetic (PK) testing for clinical trials
- YoY Revenue Growth



## PROMARKER – PLATFORM TECHNOLOGY

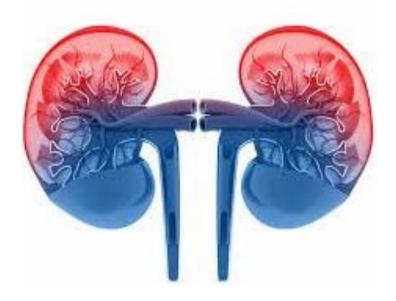


Promarker is platform technology that can identify unique protein biomarkers 'fingerprints'



The platform identifies and links the unique protein biomarkers to specific diseases, enabling Proteomics to formulate commercial diagnostic tests

# PromarkerD



## **PREDICTIVE TEST FOR DIABETIC KIDNEY DISEASE**



## A MAJOR OPPORTUNITY

### THE PROBLEM

- 425 million people have diabetes
- 1 in 3 diabetic adults currently develop chronic kidney disease
- There are no early symptoms of diabetic kidney disease. Kidney function can fall below 15-20% with no symptoms.
- There is currently no available test for predicting the onset of diabetic kidney disease
- Diabetic kidney disease leads to dialysis (US\$72,000 p.a.) or kidney transplant
- Total cost of diabetic kidney disease = US\$100Bn

### THE SOLUTION

#### **PromarkerD: A predictive diagnostic test for diabetic kidney disease**

- PromarkerD can diagnose diabetic patients already suffering from chronic kidney disease that the current gold standard tests miss
- PromarkerD can predict the onset of disease before clinical symptoms appear
- Doctors can then prescribe an early therapeutic treatment to stop the onset of disease



## HOW IT WORKS

PromarkerD is a blood test that measures plasma protein biomarkers combined with simple clinical factors to predict risk of kidney decline in people with type 2 diabetes

- > The test measures a fingerprint of 3 proteins found in a standard blood sample
- These measurements are combined with 3 clinical markers (age, cholesterol, eGFR)
- Raw data is submitted to the <u>www.PromarkerD.com</u> hub and a report is returned to the testing laboratory

#### With PromarkerD







## MAJOR COST/BENEFIT FACTOR TO DRIVE UPTAKE

With PromarkerD	Without PromarkerD		
Unequivocal Cost Benefit			
Test Price <b>US\$50 – US\$70</b> Predicts kidney disease with 86% accuracy up to four years out	Dialysis cost <b>US\$72,000</b> per year /S ongoing for the patient's life		
Unequivocal Patient Benefit			
Non invasive blood test Patients can alter habits / receive treatment to stop onset of the disease	/S Dialysis machine for term of life		



## VALIDATION COMPLETE

PromarkerD developed and validated in clinical studies of 792 patients with diabetes

**Eight year clinical journey complete - minimal clinical risk - 86% Accurate** 

Study - 1,500 people over 6 years with UWA presented to American Diabetes Association

**Results peer reviewed 2017** 

Test designed and validated for certified laboratory use

Independent review by Frost and Sullivan confirms Proteomics as the world leader in kidney disease diagnostics 2017

Kit version completed Nov '18, performance verified and commercial shipment imminent

Licensing deals executed in USA, Mexico, Spain & Dominican Republic



## TWO TYPES OF TESTS TO CAPTURE MASS MARKET

#### LABORATORY DEVELOPED TEST ("LDT")

- Utilises 'mass spectrometry' to identify specific biomarkers of proteins
- Mass spectrometers are common in laboratories throughout most developed nations
- The LDT permits fast adoption of a new test in advanced markets
  - Faster regulatory pathway
- Clinically validated First Sales imminent

#### **EXAMPLE – MAYO CLINIC**

 The Mayo Clinic or similar reference laboratories are US Nationally certified and are authorised to perform new diagnostics tests such as PromarkerD

#### **KIT VERSION**

- Immunoassay kit that utilises 'key antibody reagents' to identify the specific biomarker proteins
- Does not require a mass spectrometer
- Used by most pathology clinics, especially India, China, Japan
- Takes 9-18 months to get regulatory approval in each region
- Clinically validated First Sales imminent

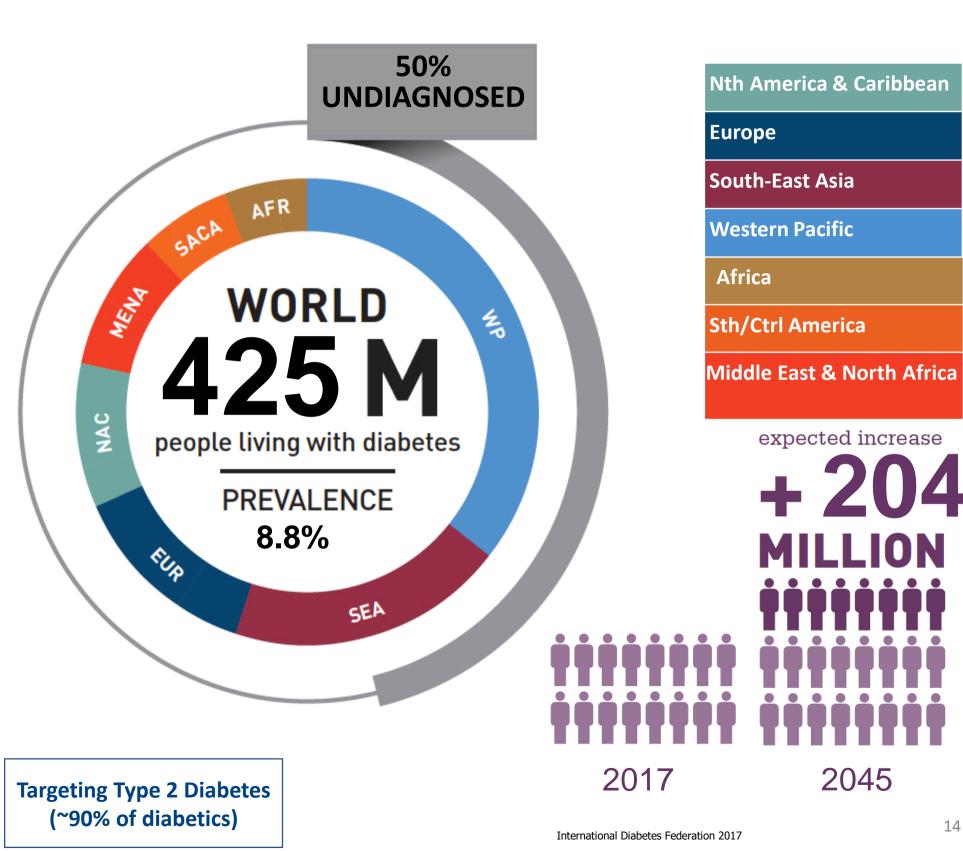
#### **EXAMPLE – DOMINICAN REPUBLIC**

- Regulatory Approval Required (i.e. equivalent of 510k or CE Mark)
- The Service Provider, in conjunction with Clinicians & Insurers, engaged with Regulatory Authorities for Kit Test approval due to significant unmet need

## MARKET SIZE?

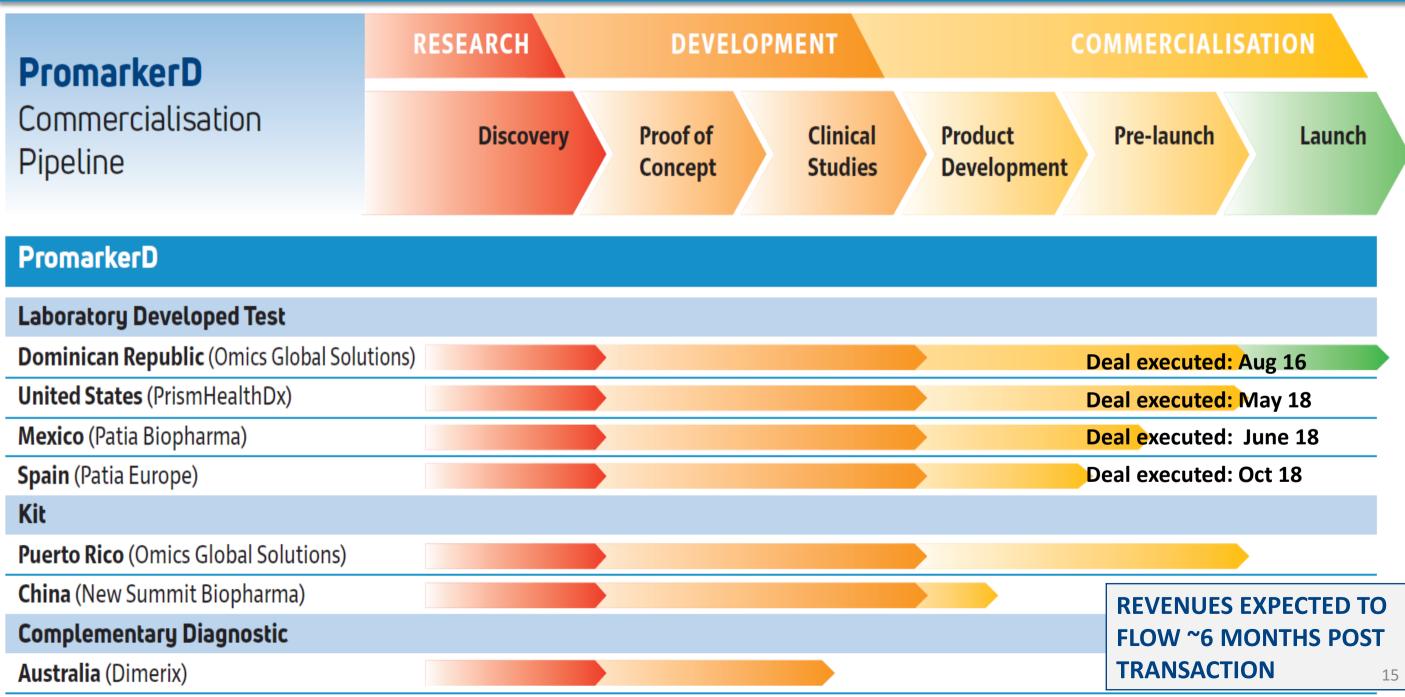
> Hundreds of millions of people could benefit from this test in terms of early treatment to mitigate the onset of kidney disease. Kidney disease is one of the major complications of diabetes which is fatal unless managed by dialysis which is costly and detrimental to quality of life.

 $\succ$  Globally, kidney disease and the diabetes epidemic cost health systems \$850 billion in 2017.





## COMMERCIAL ROLLOUT – SALES IMMINENT



## LICENSING DEAL: UNITED STATES

**PrismHealthDx, Inc. (PHDx)** is a precision medicine diagnostic laboratory and services company specialising in comprehensive biomarker testing to detect the onset of disease and serious medical conditions at their earliest and most treatable stage.

PIQ can execute additional licensing agreements in the USA to accelerate rollout (from May 2019).

### THE DEAL

- ▶ USA license agreement with **PrismHealthDx, Inc**. Executed May 2018
- The license is for the "Laboratory Developed Test" version of PromarkerD
- National launch and first revenues imminent
- ▶ 1 year exclusivity
- No rollout/marketing costs and minimal variable cost per test for PIQ

## THE US MARKET

#### 30m people with diabetes

- Kidney disease is responsible for 48,000 deaths
- Related healthcare spending tops US\$50 billion a year

## THE OPPORTUNITY

- Test price circa US\$50 US\$60 (existing reimbursement code established)
- ▶ PIQ to receive royalty per test (industry standard 5% 15%)

#### POTENTIAL OPPORTUNITY = US\$165M PER ANNUM

## LICENSING DEAL: MEXICO

Patia Biopharma offers medical community an array of genomic, metabolomic and proteomic tests for risk assessment and early diagnosis, which support early interventions in patients with diabetes.

**Carlos Slim Foundation** has benefited millions of people through high-impact programs focused on the most vulnerable population in Latin America.

### THE DEAL

- Mexico license agreement with Patia Biopharma Executed June 2018
- License deal brokered by Carlos Slim Foundation, a supporter of Patia
- The license is for the "Laboratory Developed Test" version of PromarkerD
- Imminent revenues from launch into private hospitals & clinics, followed by expansion into government hospitals and Carlos Slim Foundation programs
- 3 year exclusivity
- No rollout/marketing costs and minimal variable cost per test for PIQ

### THE MEXICAN MARKET

- Mexico has one of the highest rates of diabetes in the world
- 13m people with diabetes

### THE OPPORTUNITY

- Test price circa US\$50
- ▶ PIQ to receive royalty per test (industry standard 5% 15%)
- POTENTIAL OPPORTUNITY = US\$65M PER ANNUM

## LICENSING DEAL: SPAIN

**Patia Europe** is established in Spain as a subsidiary company of Patia Biopharma Mexico. Patia Europe offers medical community an array of genomic, metabolomic and proteomic tests for risk assessment and early diagnosis, which support early interventions in patients with diabetes.

### THE DEAL

- Spain license agreement with Patia Europe Executed October 2018
- The license is for the "Laboratory Developed Test" version of PromarkerD
- **First sales are anticipated to be within six months**
- 2 year exclusivity
- No rollout/marketing costs and minimal variable cost per test for PIQ

### THE SPANISH MARKET

- The incidence of diabetes is increasing rapidly in Spain
- 3.6m people with diabetes

### THE OPPORTUNITY

- Test price circa US\$50
- ▶ PIQ to receive royalty per test (industry standard 5% 15%)

#### POTENTIAL OPPORTUNITY = US\$18M PER ANNUM



## LICENSING DEALS

LICENSING DEALS	# DIABETICS	
United States	30m	
Mexico	13m	
Spain	3.6m	
Dominican Republic	0.5m	
TOTAL	47.1m	

PIPELINE	
Japan	10m
India	32m
China	114m
Puerto Rico	0.4m
Australia	1.2m
TOTAL – People w/ Diabetes	<u>157.6m</u>





## INTELLECTUAL PROPERTY

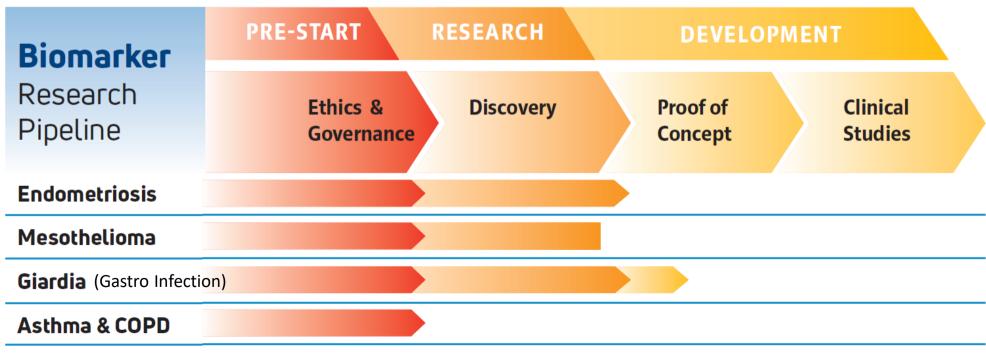
Countries with granted IP	Patents	Trademark	
USA	$\checkmark$	$\checkmark$	
Europe	$\checkmark$	Pending	
Australia	$\checkmark$	$\checkmark$	
China	$\checkmark$	$\checkmark$	
Japan	$\checkmark$	$\checkmark$	
Russia	$\checkmark$		
Singapore	$\checkmark$	Pending	
National phase patent examination pending: Brazil, Canada, India and Indonesia			

### **PATENT EXPIRY: 2031**

## DIAGNOSTICS PIPELINE

### FURTHER GLOBAL POTENTIAL IN NEW MARKETS

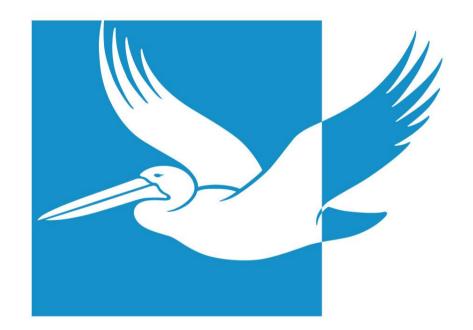
- ▶ Proteomics endeavours to leverage its <u>Promarker<sup>TM</sup></u> Platform to develop and commercialise a suite of diagnostic tests
- Potential for faster market adoption for new diagnostic test, post a successful PromarkerD commercialisation
- Enormous markets and revenue potential for PIQ



The Promarker<sup>™</sup> research pipeline and typical timeline is:

- Ethics & gov approval (3 months)
- Discovery (3-6 months)
- Proof of concept (3-6 months)
- Clinical studies (12 months)

# **ANALYTICAL SERVICES**



## **REVENUE GENERATING BUSINESS WITH SYNERGIES**



## ANALYTICAL SERVICES

### WORLD'S FIRST COMPANY TO RECEIVE ISO 17025 LABORATORY ACCREDITATION FOR PROTEOMICS SERVICES

#### **Biosimilars & biologics**

- Assisting pharmaceutical companies develop biosimilar drugs "generics"
- Biosimilar generic development begins with extensive structural and functional characterisation which underpins all further product development activities
- Proteomics' services deliver immediate, independent and affordable assistance in demonstrating biosimilarity, (i.e. that the compound is the same as the original)

#### Pharmacokinetic testing (PK) for clinical trials

- Pre-clinical and clinical quantitative assays for any investigational drug
  - Measures drug stability in patients
  - Leverages a wealth of expertise in building novel assays
  - Synergies with biomarker discovery to create new Complementary Diagnostic tests (CDx)
  - A CDx can be used to assess a patient's early response to a new drug

PROTEOMICS' ANALYTICAL SERVICES HAVE DELIVERED YoY REVENUE GROWTH, SUCCESSFULLY OFFSETTING THE R&D COSTS



## MILESTONES AND UPCOMING CATALYSTS

### **ACHIEVED MILESTONES**

- ✓ PromarkerD predictive test clinically proven
- ✓ Patents granted in USA, China, Europe & Japan
- ✓ PromarkerD results published in leading journals
- ✓ Independent market assessment (Frost & Sullivan)
- ✓ PromarkerD licensed in USA, Mexico & Spain
- ✓ PromarkerD launched in Dominican Republic
- ✓ PromarkerD kit production
- ✓ An 8 year journey now complete!
- ✓ Sales imminent

### **SHARE PRICE CATALYSTS**

#### **PromarkerD**

**Revenue commences from royalties** Further licencing deals in major territories Launch of PromarkerD Kit Version Expansion of deals in existing territories Patents in other global jurisdictions Diagnostic capability to assist drug developers to market kidney disease treatments **Analytical services** Revenue growth from biosimilars & PK testing **Diagnostic test development** Endometriosis, gastro, asthma and lung disease

Pipeline expansion into other chronic diseases



## EXCEPTIONAL GLOBAL OPPORTUNITY

- ✓ A proven diagnostics business with truly global potential
- ✓ Scalable licensing model with high margins and negligible rollout cost
- ✓ Minimal burn rate ensures rollout is funded
  - Established revenue reduces burn, trending to cash flow positive
- ✓ Strong IP position
  - Patents granted in major jurisdictions for pioneering PromarkerD diagnostic test
- ✓ Proven technology platform pipeline of potential globally significant tests
  - Proof of concept established with PromarkerD: Endometriosis, asthma, etc undergoing pre-clinical work
- ✓ World leading technology in an area of significant unmet medical need
  - Frost & Sullivan identifies "high adoption potential" for PromarkerD
  - Current and pending deal flow amidst fast-growing international activity

Region	Diabetics	<b>Potential Test Price</b>	Industry Royalty	Potential Opportunity	
USA	30m	US\$50-60	5% - 15%	US\$165m p.a.	POTENTIAL US\$248M
MEXICO	13m	US\$50	5% - 15%	US\$65m p.a.	P.A. REVENUE OPPORTUNITY
SPAIN	3.6m	US\$50	5% - 15%	US\$18m p.a.	OPPORTOINTT

## BOARD & MANAGEMENT DIRECTORS HOLD 35%



#### Terry Sweet FAICD, Chairman

Director of several listed companies over the past 30 years in both executive and non-executive capacities. Companies include XRF Scientific Ltd, where he was Managing Director for 4 years, Western Biotechnology Ltd, Heartlink Ltd, and Scientific Services Ltd.

## **Richard Lipscombe** PhD (London), MA (Oxon), Founder & Managing Director Successfully managed the Company for 17 years.

30 years experience in research and development globally in academic and commercial entities. Technical expertise in chemistry, immunology, & biomarker discovery.



#### John Dunlop PhD (UWA), BSc (UWA), Non-Executive Director

Director of several ASX-listed companies covering mineral exploration, finance & analytical labs. Founding Director of beta-carotene producer Western Biotechnology Ltd and Founding Director of Sheen Analytical Services (which listed as Scientific Services Ltd).



#### Roger Moore R (Denmark), BPharm (U.Syd), Non-Executive Director

International pharmaceutical industry experience spanning 40 years, including almost 30 years as President of Novo Nordisk Japan. From 2000, he was appointed Novo Nordisk's Senior Vice President, Japan and Oceania Region. He has also served as a member of the Senior Management Board, Novo Nordisk A/S.



#### Paul House GAICD, BCommerce (UWA), Non-Executive Director

Over 25 years with multi-national corporations, most recently serving as MD, SGS India for 8 years. Previously held CFO and COO roles, and was Senior Manager at a leading global management consultancy firm.



#### Chuck Morrison BSc (Boston), MBA (Boston), Business Development

36 years in life sciences, biotechnology, and diagnostic industries including DuPont and PerkinElmer.

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## **Proteomics International**

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